

## REMARKS

This amendment accompanies a Request for Continued Examination. Applicants respectfully request entry of this amendment before further consideration.

This paper is filed in response to the Office Action issued June 27, 2008. Claims 1, 4-14 and 17-22 had been presented. The Office Action rejected these claims for the reasons detailed below. Claims 2-3, 15-16 and 23-24 were cancelled in a previous response. Claim 1 has been amended. Claims 25-28 have been added. Claims 1, 4-14, 17-22, and 25-28 are pending.

### Rejections under 35 U.S.C. § 102(b)

Claims 1, 4-10, 14, and 17-19 were rejected under 35 U.S.C. § 102(b) as allegedly unpatentable over U.S. Patent No. 5,733,294 to Forber et al. (herein "Forber"). Applicants have amended claim 1 and respectfully request reconsideration.

Amended claim 1 now recites a patent foramen ovale (PFO) closure device for providing compressive force to septum primum and septum secundum including a central body, a first and second end cap, and a first and second wire extending from the first end cap to the second end cap. The first wire and the second wire define first and second loops on one side of the PFO and third and fourth loops on the other side of the PFO. Each of the first and second loops extend from the central body to the first end cap. Each of the third and fourth loops extend from the central body to the second end cap. Each of the first and second loops define a first plane substantially parallel to septum primum and septum secundum, and the first and second loops cooperate with the central body to apply a force, perpendicular to the first plane, to overlapping layers of septum primum and septum secundum. Each of the third and fourth loops define a second plane substantially parallel to septum primum and septum secundum, and the third and fourth loops cooperate with the central body to apply a force, perpendicular to the second plane, to overlapping layers of septum primum and septum secundum. The first and second wires are not overlapped by another wire in the first and second planes when in the deployed configuration.

Forber does not teach or suggest the recited combination of amended claim 1.

Thus, applicants respectfully traverse these rejections as Forber does not teach or suggest all of the limitations of amended claim 1. Specifically, Forber lacks first and second wires that define first and second loops on one side of the PFO and third and fourth loops on the other side of the PFO, wherein the first and second wires are not overlapped by another wire in the first and second planes when in a deployed configuration.

Forber discloses devices for cardiovascular occlusion. Forber describes a device that has a predetermined pattern of wires helically wound in a braided pattern. Forber states that the primary use of the device is in embolotherapy to occlude blood vessels. See Forber at col. 3, lines 16-39. Forber also states that the device may be used to close a septal defect and illustrates, in Figs. 6-8, a device with two annular wire mesh disks. The device is shown in a septal defect such that one wire mesh disk is on either side of the septal defect. The wire mesh disks are composed of wires that overlap each other in the plane defined by the wire loops. See Forber at col. 3, lines 16-67, col. 5, line 54-col. 6, line 2, and Fig. 8.

Thus, applicants submit that Forber does not describe a device with first and second wires that define first and second loops on one side of the PFO and third and fourth loops on the other side of the PFO, wherein the first and second wires are not overlapped by another wire in the first and second planes when in a deployed configuration.

The braided nature of the wire mesh disks set forth in Forber prevent the disks from performing as required by claim 1. In addition, the overlapping layers of tissue would cause the center tubular portion to tilt at an angle within the defect, thereby assuming a non-perpendicular angle relative to the overlapping layers of tissue. Because the disks 130 and 132 are a braided mesh attached to the center tubular portion, the disks, when deployed, will tend to remain in a plane that is normal to the axis of the center tubular portion. Thus, as the center tubular portion tilts, disks 130 and 132 will also tilt relative to the overlapping layers of tissue. Thus, the plane of deployed disks 130 and 132 would no longer be parallel to the septum primum and septum secundum so as to provide a compressive force to these layers. Therefore, Forber also lacks any teaching or suggestion of a device having structure adapted

to provide compressive force to overlapping layers of tissue or the desirability of such structure.

In contrast, amended claim 1 clearly recites that the first and second wires are not overlapped by another wire in the first and second planes when in the deployed configuration. The features recited in claim 1 enable the device to be used with small diameter delivery sheaths, have reduced metal mass, and be manufactured easily and at reduced cost. Moreover, the configuration of the loops provides generally evenly distributed pressure along the defect axis to promote closure of the PFO defect. See Application at pg. 5, line 21-page 7, line 17.

In addition, claim 1 recites the loops of the PFO closure device apply a force to overlapping layers of septum primum and septum secundum in a direction perpendicular to a plane substantially parallel to the septum primum and septum secundum. This compressive force acts to pinch the PFO defect closed. As described in the application, the configuration of elements recited in amended claim 1 may assume a skewed configuration relative to a line perpendicular to the septum primum and septum secundum. This flexibility between the central body, end caps, and wire loops enables the device to provide the compressive force to the overlapping layers of tissue. See Application at pg. 6, lines 4-26.

Therefore, because Forber does not teach or suggest all of the limitations of amended claim 1, claim 1 is patentable over Forber.

Claims 4-14, 17-22, and 25-28 depend from claim 1. Thus, these claims include the combination recited in claim 1 and are patentable over Forber for at least the same reasons as claim 1.

Rejections under 35 U.S.C. § 103(a)

Claims 11, 13, and 20 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Forber in view of U.S. Patent No. 6,117,159 to Huebsch et al. (herein "Huebsch"). Claims 12 and 21-22 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Forber in view of Huebsch and in further view of U.S. Patent No.

6,355,052 to Neuss et al. (herein "Neuss"). Specifically, the Office Action states that Forber discloses the combination recited in independent claim 1, from which claims 11-13 and 20-22 depend, and relies on Huebsch and Neuss to provide the additional limitations set forth in the dependent claims.

As set forth in detail above, Forber does not teach or suggest all of the limitations of independent claim 1. Neither Huebsch nor Neuss provide these missing elements. Thus, claims 11-13 and 20-22 are patentable over the cited references for the same reasons given above for independent claim 1.

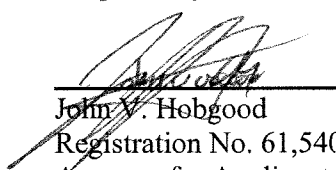
Conclusion

Applicants respectfully request an early and favorable reconsideration and issuance of this application as amended herein. The Examiner is encouraged to contact the undersigned to expedite prosecution of this application.

An authorization to charge the fees for the Request for Continued Examination accompanies this response. No other fees are believed to be due in connection with this response. However, please charge any fees due in connection with this application or credit any overpayments to Deposit Acct. No. 08-0219.

Respectfully submitted,

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